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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,671	05/15/2001	Takahiro Ochi	017498-0155	1143

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EXAMINER

SAUCIER, SANDRA E

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/854,671

Applicant(s)
Ochi

Examiner
Sandra Saucier

Art Unit
1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 4, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

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DETAILED ACTION

Claims 1-42 are pending and are considered on the merits.

Election/Restriction

Applicants election of species in paper # 7 is acknowledged.

Claim Rejections – 35 USC § 112

INDEFINITE

Claims 1-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are in poor English and refer to numbers in parenthesis. It is unclear to what these numbers refer and what exactly is being claimed.

For example, what does the term “compactly” sintered mean, what is a skeletal part, what is the relationship between the skeletal part and the calcium phosphate, what is the relationship between the pores, what shape is a globular pore, what is the meaning of the % in terms of porosity, that is how is it measured? Usually a % requires definition of both upper and lower terms, e.g. wt/wt, wt/vol etc., what is grain growth, what is a compact skeleton? The independent claims cannot be understood in their present form.

Please be careful not to introduce new matter or to expand the original claims when redrafting.

Claims 1, 2, 16 and others mention % porosity. However, the manner in which it is measured affects the value of the determination. The method of measurement is not clear.

Claim 6 is a product claim, but appears to have some process steps.

Claims 12, 22, 29, what is an active material? Any material may be “active” under certain circumstances.

Claim 19 is unclear. What is a glass for a living body? This does not appear to be a term of art. Is the glass calcium phosphate or calcium titanate? The structure of the claim makes it undecipherable.

Claims 33 and 34 are completely undecipherable.

Claim 35, what is the meaning of “dense” microstructure. Where is the

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microstructure, where is the microstructure, how big is a microstructure, what relationship does it have with other parts of the claimed article, how dense is dense?

Claim 37 has parenthetical inclusion which may be meant to further limit the preceding claim or not?

Claim 41 which is a method claim has no active steps and cannot be understood.

Claim 42 refers to numbered items which have no relationship to any structure.

Please carefully revise these claims so that prosecution may be advanced.

The examiner has tried to apply the art to these poorly drafted claims to the extent that they could be understood in the light of the poorly written or translated specification.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 16-21, 25-28, 33-35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 93/04013 [A2].

The claims are directed to a biomaterial comprising a porous body of sintered calcium phosphate with globular pores with a porosity of 55-85%.

The references are relied upon as explained below.

WO 93/04013 discloses a method of making a sintered porous article for replacing a body member comprising hydroxyapatite, see examples III, VIII and page 10, middle paragraph.

Claims 1-10, 16-21, 25-28, 33-35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 98/38948 [N].

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WO 98/38948 discloses an implant comprising an internal support structure and an external coating of hydroxylapatite with a porosity of 40-80% having interconnected pores with a diameter of 600-1000 microns (page 6, l. 10-15), see entire application.

Claims 1-10, 16-21, 25-28, 33-42 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 98/20549 [M].

WO 98/20549 discloses an implant comprising an inner metal support with a void volume of less than 10% (page 11), an intermediate layer and a foamed and sintered hydroxyapatite outer layer with a porosity of up to about 50 volume percent pore space, example 4) and interconnecting pores is disclosed. See entire application.

Claims 1-10, 12, 13, 15-22, 25-29, 32-42 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by US 6,340,648 [A].

US 6,340,648 discloses an implant comprising an inner part and an outer calcium phosphate sintered part with a porosity of 55-90% with a pore diameter of 150 microns or more and interconnecting pores. The article is formed by foaming with a resin and sintering. The article may be impregnated with a drug, see entire patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-15, 22-24, 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/20549 [M] or WO 98/38948 [N] or US 6,340,648 [A] in combination with Chistolini *et al.* [U] or Itokazu *et al.* [V].

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The claims are directed to the addition of cells or "active materials" in the pores of the formed article.

The references are relied upon as explained below.

WO 98/20549, WO 98/38948 and US 6,340,648 have been explained above.

Itokazu *et al.* disclose that porous hydroxyapatite may be loaded with antibiotic or anticancer drugs prior to implantation.

Chistolini *et al.* disclose that porous hydroxyapatite may be loaded with cells prior to implantation.

The addition of drugs or cells into the porous implant disclose in WO 98/20549 or WO 98/38948 or US 6,340,648 would have been obvious when taken with Itokazu *et al.* or Chistolini *et al.* who disclose such an addition.

One of ordinary skill in the art would have been motivated at the time of invention to make this addition of drugs or cells to the porous implant in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.



Sandra Saucier
Primary Examiner
Art Unit 1651
February 6, 2003